Medacta International

JUL 05 2013

510(k) Summary

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Contact Person: Mr. Adam Gross
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Date Prepared: June 7, 2013

DEVICE INFORMATION

Trade/Proprietary Name: MectaLIF Extension
Common Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Fusion Device with Bone Graft, Lumbar

21 CFR 888.3080
Class II
Device Product Codes: MAX

Predicate Devices:

510(k)	Product	510(k) Holder	Clearance Date
K110927	MectaLIF Posterior and Oblique	Medacta International	6/13/2011
K120024	MectaLIF Transforaminal	Medacta International	2/28/2012
K072791	OPAL Spacer	Synthes	12/26/2007
K040536	Boomerang	Medtronic	5/5/2004
K073291	Capstone	Medtronic	04/24/2008
K081917	Devex/Leopard	Depuy Spine	5/22/2009
P960025	Lumbar IF Cage	Depuy Acromed	2/2/1999

Product Description

MectaLIF Extension is a design modification to MectaLIF Posterior and Oblique (K110927) and MectaLIF Transforaminal (K120024). The bullet nose modification to the implant tip geometry creates a self-distracting feature which facilitates insertion of the implant into the disc space. MectaLIF Extension also includes intermediate sizes of MectaLIF Posterior and Oblique as well as new sizes of MectaLIF Oblique. The materials and indications for use are identical to the predicate devices. The materials are PEEK-OPTIMA LT1: Implant Grade Polyetheretherketone (ASTM F 2026) and Tantalum (ISO 13782 / ASTM F 560). MectaLIF Transforaminal also has a Gear made of Titanium: Ti6Al4V ELI (ISO 5832-3/ASTM F 136). The devices are intended to be used in combination with posterior fixation (e.g. Pedicle Screw System) as well as an autogenous bone graft.

Indications for Use

The MectaLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Comparison to Predicate Devices

The indications for use and materials of the MectaLIF Extension are identical to the previously cleared predicate devices. The design features, geometries, and sizes of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the MectaLIF Extension are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

Performance Testing

The modification to the device system to include the addition of MectaLIF Extension was evaluated by risk analysis to identify any new risks associated with the change. Based on the risk analysis, design verification was conducted to written protocols with pre-defined acceptance criteria. The protocols and pre-defined acceptance criteria were based on the standards, FDA guidance, and comparison to the predicate device system. The testing was conducted on the worst case component size and

option/design based on engineering analysis. The MectaLIF Extension was compared to the worst case of the predicate devices and it was determined that the MectaLIF Extension are not worst case.

MectaLIF Extension has similar performance testing as the predicates in terms of:
Static Axial Compression - ASTM F2077
Dynamic Axial Compression - ASTM F2077
Static Compression/Shear - ASTM F2077
Dynamic Compression/Shear - ASTM F2077
Subsidence Resistance - ASTM F2267

Conclusion:
Based on the above information, the MectaLIF Extension can be considered as substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 5, 2013

Medacta International SA
% Mr. Adam Gross
Director of Regulatory, Quality and Compliance
4725 Calle Quetzal, Unit B
Camarillo, California 93012

Re: K131671
Trade/Device Name: MectaLIF Extension
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 7, 2013
Received: June 7, 2013

Dear Mr. Gross:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131671

Device Name: MectaLIF Extension

Indications for Use:

The MectaLIF implants in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion. Degenerative disc disease is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). Patients must be skeletally mature. Patients should have received 6 months of non-operative treatment prior to treatment with the devices.

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices